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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/007,061	11/30/2001	Robert R. Gonnelli	BVTP-P03-007	6208

7590 06/15/2005

Patent Group  
Ropes & Gray  
One International Place  
Boston, MA 02110

EXAMINER
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HOGAN, JAMES SEAN

ART UNIT	PAPER NUMBER
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3752

DATE MAILED: 06/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/007,061

Applicant(s)

GONNELLI ET AL.

Examiner

James S. Hogan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 April 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9, 11-13 and 15-18 is/are rejected.
- 7) ☒ Claim(s) 10 and 14 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 June 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 12/27/2004.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 15 provides for the use of "igniting a charge", but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 15 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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2. Claims 1-9 and 11-13 rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,270,473 to Schwebel in view of U.S. Patent No. 6,830,560 to Gross et al.

As per claims 1 and 11-13 Schwebel ('473) teaches a needleless (i.e. jet injector) injection device integrally formed comprising an injector having a first cavity (92) and an orifice (16). The injection device includes a movable member (20) in the first cavity (see Fig. 3) and a charge (12) in a housing (100) having a second cavity (104). Schwebel ('473) teaches the charge containing a propellant. Schwebel ('473) does not teach the charge being comprised of having at least two layers. The device of Gross et al. ('560) teaches a gas-generator using a charge of two materials used in an automatic syringe. As per claim 2, the materials of Gross et al. ('560), citric acid and sodium bicarbonate, have different combustion characteristics. As per claim 3 and 4, the charge of Gross et al. ('560) is staged in two layers (upper chamber 29 and lower chamber 31), adjacent to each other (see Figure 4). As per claim 5, 8 and 6, as reasonably understood, sodium bicarbonate can be considered a trigger, and citric acid can be considered the propellant. As per claim 7 and 9, the charge of Gross et al. ('560), further comprises a passive decay material, membrane (34). It would have been obvious to one skilled in the art at the time the invention was made to have substituted the charge of Schwebel ('473) with the charge of Gross et al. ('560) in order to provide a charge in a needleless injector that is made up of non-lethal chemical components.

3. Claims 15-18 rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,270,473 to Schwebel in view of U.S. Patent 5,421,264 to Petrick.

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Regarding claims 15-18, as best understood, the device of Schwebel ('473) teaches in its assembly makeup of a needleless injector the process of igniting a charge in an injector having an office for needleless injection so that fluid in a cavity in the injector is ejected out of the cavity. Schwebel ('473) teaches the use of a "Winchester large rifle primer, which contains 350 mg. of azide"" (Col. 9, line 1) as a charge. Schwebel ('473) does not disclose the use of a two-layer charge. As per claim 18, the embodiment disclosed in figure 13 of Petrick ('264) teaches a layered charge for having a predetermined result having two discrete materials, boron potassium nitrate as a trigger material (1308) and smokeless gunpowder (1306) as a main propellant; Col. 13, line 3-16). It would have been obvious to one skilled in the art at the time the invention was made to have substituted the charge of Schwebel ('473) with the charge of Petrick ('264) in order to provide a charge in a needless injector with a desired pressure-rated result.

***Allowable Subject Matter***

4. Claims 10 and 14 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Conclusion***

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure is as follows:

U.S. Patent No. 6,758,829 to Alexandre et al., disclosing a needleless syringe

U.S. Patent No. 6,835,187 to Alexandre et al., disclosing a needleless syringe

U.S. Patent No. 6,708,621 to Forichion-Chaumet et al., disclosing an igniting device

U.S. Patent No. 6,740,062 to Hjertman, disclosing a medical device

U.S. Patent No. 6,406,455 to Willis et al., disclosing an injection device

U.S. Patent No. 6,881,200 to Bellhouse et al., disclosing a needleless syringe


Any inquiry concerning this communication or earlier communications from the examiner should be directed to James S. Hogan whose telephone number is (571) 272-4902. The examiner can normally be reached on Mon-Fri, 7:00a-4:00p EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Scherbel can be reached on (571) 272-4919. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JSH  
06/08/2005



**David A. Scherbel**  
**Supervisory Patent Examiner**  
**Group 3700**